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5 IN THE UNITED STATES DISTRICT COURT
6 FOR THE EASTERN DISTRICT OF WASHINGTON

7 JEREMY OLSEN,

8 Plaintiff,

9 v.

10 XAVIER BECERRA, in his official
11 capacity as Secretary of the United
12 States Department of Health and
Human Services,

Defendant

No.

COMPLAINT FOR
ADMINISTRATIVE REVIEW,
DECLARATORY RELIEF,
INJUNCTIVE RELIEF, AND
APPOINTMENT OF A
SPECIAL MASTER

JURY TRIAL DEMANDED

13 1. Plaintiff Mr. Jeremy Olsen brings this action against Defendant
14 Xavier Becerra, in his official capacity as Secretary of the United States
15 Department of Health and Human Services. Plaintiff makes the following
16 allegations based on the investigation of counsel and on information and on
17 personal knowledge.

18 **I. INTRODUCTION**

19 2. This litigation is the result of the Secretary's continued bad
20 faith in considering claims for continuous glucose monitor (CGM)

1 coverage. Mr. Olsen previously filed suit in this Court and obtained a
2 judgment ordering coverage of his CGM claims. *See Olsen v. Becerra*, E.D.
3 Wa. Case No. 20-cv-374 (SMJ) (hereinafter, “*Olsen I*”). This Court further
4 found that the Secretary’s base position (*i.e.*, that a CGM is not “primarily
5 and customarily used to serve a medical purpose”) was frivolous and in “bad
6 faith.” Further, the Court determined that the Secretary had engaged in bad
7 faith and vexatiousness during the course of the litigation. As a result (on
8 information and belief), for only the eleventh time in the past 10 years,¹ the
9 United States was found to have engaged in “bad faith” and this Court
10 awarded attorneys fees at market rates to Plaintiff. *Id.* at Dkt. #50 (April 20,
11 2021).

12 3. Incredibly, *after* this Court’s “bad faith” finding, the Secretary
13 has continued to reject CGM claims, including Mr. Olsen’s claims, on the
14 same “bad faith” grounds (*i.e.*, that a CGM is not “primarily and customarily
15 used to serve a medical purpose” as construed in CMS 1682-R or standing
16 alone).

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19 ¹ Based on investigation of counsel, during this period, the United States
20 was a party to well more than one million cases.

1 4. In addition to the basic continued denial of Mr. Olsen's claims
2 on the "bad faith" grounds, the Secretary has also engaged in "bad faith" in
3 an effort to delay/avoid judicial review. In particular, in defiance of
4 Congress' intent, the Secretary (through his appointees, the Departmental
5 Appeals Board) in "bad faith" denied Mr. Olsen's request for "expedited
6 access to judicial review" on the grounds that something other than illegally
7 issued CMS 1682-R barred coverage, when the only basis for denial was
8 CMS 1682-R and an ALJ had already ruled that *only* CMS 1682-R barred
9 coverage of the claim at issue.

10 5. Thus, the Secretary sought to prolong the "bad faith" process
11 and subject Mr. Olsen to increased delay and expense through his "bad
12 faith" handling of Mr. Olsen's claims.

13 6. Because of the repeated instances of "bad faith" conduct, this
14 suit seeks to have Mr. Olsen's claims covered, set aside CMS 1682-R and
15 enjoin its use to reject CGM claims, and place CGM claims denials under
16 this Court's supervision through a special master for a limited period of time
17 until the Court is satisfied that the Secretary will not engage in "bad faith"
18 conduct in considering such claims and jeopardizing the lives of
19 beneficiaries.

II. JURISDICTION

7. This Court has jurisdiction over this action pursuant to 42 U.S.C. §§ 405(g) and 1395ff. Mr. Olsen is filing suit after a final decision(s) of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of his Medicare claim (and, therefore, has exhausted his administrative remedies), the amount-in-controversy is more than \$1,600 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary's final decision.

8. In addition, for one of the claims at issue, jurisdiction over this action is proper pursuant to 42 U.S.C. §§ 405(g) and 1395ff because Plaintiff has presented his claim, had been denied, and further process would be futile. Alternatively, for that same claim, jurisdiction is proper under 42 U.S.C. § 1395ff(b)(2) because Plaintiff utilized the expedited access to judicial review procedure and the Secretary did not issue a decision by a neutral decision maker within 60 days.

9. Venue is proper in this district pursuant to 42 U.S.C. § 405(g) and 42 U.S.C. § 1395ff(b)(2)(c)(iii) because this action is being brought in the Eastern District of Washington.

1 **III. PARTIES**

2 10. Plaintiff Jeremy Olsen is an individual and a resident of the
3 State of Washington. Mr. Olsen is eligible for Medicare on the basis of
4 disability as previously determined by the Secretary.

5 11. Defendant Xavier Becerra sued in his official capacity as the
6 Secretary of Health and Human Services.

7 **IV. FACTUAL BACKGROUND**

8 12. In the interests of brevity, Plaintiff will not repeat general
9 information/allegations regarding diabetes and the Medicare appeals
10 process. For this information, Plaintiff refers the Court to the prior case:
11 *Olsen v. Azar*, E.D. Wa., Case No. 20-cv-374 (SMJ).

12 **A. Durable Medical Equipment**

13 13. Medicare covers “durable medical equipment.” Pursuant to 42
14 U.S.C. § 1395x(n), “durable medical equipment” is not defined, except by
15 example.

16 14. One such example is “glucose monitors.”

17 15. The Secretary has issued regulations further setting forth a five-
18 part test to determine whether equipment is “durable medical equipment”
19 within the meaning of § 1395x(n) (see 42 C.F.R. § 404.202).

20 16. Equipment is considered “durable medical equipment” if it:

- a) Can withstand repeated use;
- b) Has an expected life of at least 3 years;
- c) Is primarily and customarily used to serve a medical purpose;
- d) Generally is not useful to an individual in the absence of illness or injury; and
- e) Is appropriate for use in the home.

B. CMS-1682-R

17. Pursuant to 42 U.S.C. § 1395hh(2):

No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

18. The “paragraph (1)” referred to requires “notice and comment” as described in the remainder of 42 U.S.C. § 1395hh.

19. Without notice and comment, on January 12, 2017, CMS issued Ruling No. CMS-1682-R as CMS “final opinion and order” with regard to CGM coverage.

20. By its own terms, that Ruling is “binding on all CMS components, on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration ...”

21. The Ruling addresses whether CGMs are DME and, therefore, covered within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

1 22. As set forth there, if a CGM does not completely replace finger
2 prick/test strips, CMS considers the device not “primarily and customarily
3 used to serve a medical purpose.” This is so, CMS contends, because
4 patients do not “mak[e] diabetes treatment decisions, such as changing one’s
5 diet or insulin dosage based solely on the readings of the CGM[.]” *See*
6 CMS-1682-R at 6-7. CMS calls these CGM’s “non-therapeutic.”

7 23. The Ruling determines that one CGM that has been FDA
8 approved to completely replace finger pricks/test strips is DME (the
9 Dexcom G5). *See* CMS-1682-R at 7-10. In particular, the Ruling
10 determines that the receiver/monitor portion of a CGM lasts more than 3
11 years and, including other factors, that the whole system is DME within the
12 meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

13 24. Both before and after issuance of CMS-1682-R, the Secretary
14 has refused coverage of CGM devices made by Medtronic and Dexcom
15 (other than the Dexcom G5) on the grounds that they are not “primarily and
16 customarily used to serve a medical purpose.”

17 25. Further, as a result of CMS-1682-R, the discretion ALJ’s
18 previously had to award coverage (even in the face of an alleged LCD) was
19 eliminated. As a result, it is futile to submit claims for non-Dexcom G5
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1 devices with dates of service after January 12, 2017. Because the ALJs no
2 longer have discretion, those claims must be denied.

3 26. Without notice and comment, CMS-1682-R was subsequently
4 incorporated into LCD L33822.

5 27. Without notice and comment, CMS-1682-R was subsequently
6 incorporated into Policy Article A52464.

7 28. Thus, the Ruling substituted the non-statutory/regulatory term
8 “therapeutic” for the previous non-statutory/regulatory term
9 “precautionary” as the criteria/basis for denials.

10 29. ALJs are bound by CMS Rulings and cannot determine that
11 CMS Rulings are invalid.

12 30. The Medicare Appeals Council (MAC) is bound by CMS
13 Rulings and cannot determine that CMS Rulings are invalid.

14 31. Each month, approximately 13,000 claims for CGM coverage
15 (under both Medicare Part B and Part C) are denied on the basis of CMS
16 1682-R.

17 **C. Other Litigation Related to CGMs**

18 32. In general, the Secretary has refused to cover CGMs on the
19 grounds that a CGM is not durable medical equipment. This is so, the
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1 Secretary contends, because CGMs are not “primarily and customarily used
2 to serve a medical purpose.”

3 33. Instead, the Secretary contends that a CGM is excluded from
4 coverage as “precautionary” – a non-statutory term. Although there was no
5 national or local coverage determination (NCD/LCD) excluding CGM
6 coverage, a local coverage article (LCA) described CGMs as excluded as
7 “precautionary.” LCA A52464.

8 34. The Secretary’s refusal to cover CGMs has been the subject of
9 numerous litigations.

10 35. At the Medicare Administrative Law Judge (“ALJ”) level, for
11 claims not subject to CMS 1682-R, more than 40 ALJs considered the
12 Secretary’s position that a CGM is not “primarily and customarily used to
13 serve a medical purpose” and rejected that claim more than 55 times. A
14 listing of relevant ALJ decisions may be found at
15 [http://dparrishlaw.com/wp-content/uploads/2017/11/Favorable-ALJs-on-](http://dparrishlaw.com/wp-content/uploads/2017/11/Favorable-ALJs-on-CGM2.pdf)
16 [CGM2.pdf](http://dparrishlaw.com/wp-content/uploads/2017/11/Favorable-ALJs-on-CGM2.pdf).

17 36. As to the Secretary’s base position that a CGM is not
18 “primarily and customarily used to serve a medical purpose”, that position
19 has been rejected by four district courts (not counting this one).

20

1 37. In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26,
2 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018)
3 (Crawford, J.), *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018)
4 (Gorton, J.), and *Zieroth v. Azar*, 2020 WL 5642614 (N.D. Ca. Sept. 22,
5 2020), the district courts found that the Secretary’s claim that a CGM is not
6 “primarily and customarily used to serve a medical purpose” was erroneous,
7 not supported by substantial evidence, and in each case, ordered the
8 Secretary to provide CGM coverage.

9 38. Further, in the *Whitcomb* case, the court found that the
10 Secretary’s position was “arbitrary and capricious” and “unreasonable.”
11 Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.) at 14, 12.

12 39. In addition, all four courts found that the Secretary’s position
13 lacked “substantial justification” and awarded attorney’s fees to the
14 plaintiffs pursuant to the Equal Access to Justice Act. *See* 5 U.S.C. § 504.

15 40. Likewise, the Secretary’s own Civil Remedies Division
16 concluded that exclusion of CGM coverage on the grounds that a CGM is
17 “precautionary” did not pass the “reasonableness standard.” *See* DAB No.
18 CR4596, 2016 WL 2851236 at *18.

D. Facts Specific to Mr. Olsen

41. Jeremy Olsen is a 43-year old father of three and a journeyman carpenter. In his free time, Mr. Olsen enjoys fixing up old cars, woodworking, and crafts activities.

42. First diagnosed with Type I diabetes at the age of nine (9), Mr. Olsen is a “brittle” diabetic (*i.e.*, his glucose levels are prone to wild and rapid swings). In addition, Mr. Olsen suffers from hypo/hyperglycemic unawareness (*i.e.*, he has no physical sensations – head aches, sweats, etc. – that alert him his glucose levels need to be adjusted). Prior to receiving an insulin pump and a CGM, Mr. Olsen had to be revived at the Emergency Room more than 20 times because of his uncontrolled diabetic condition.

43. To assist with management of his diabetes, Mr. Olsen was fitted with an insulin pump.

44. As a result of his diabetic condition, Mr. Olsen suffered from kidney failure. In 2016, Mr. Olsen had kidney and pancreas transplant surgery. While it was hoped that the pancreas transplant would address Mr. Olsen’s diabetes, the transplant did not succeed and Mr. Olsen continues to suffer from diabetes.

45. In 2018, Mr. Olsen was prescribed a Medtronic MiniMed continuous glucose monitor for two reasons. First, of course, given his

1 brittle diabetes and hypoglycemic unawareness, traditional finger stick
2 checking was not sufficient to manage Mr. Olsen's diabetes such that he
3 continued to suffer a risk of death and other complications. Second, out of
4 range glucose levels as a result of the diabetes jeopardize Mr. Olsen's
5 transplanted kidney.

6 46. The Medtronic MiniMed CGM communicates with Mr.
7 Olsen's insulin pump to properly regulate the amount of insulin being
8 dispensed. Since receiving an insulin pump and the CGM which interfaces
9 with it, Mr. Olsen has not had to visit the Emergency Room as a result of
10 his diabetic condition.

11 47. As a result of his diabetic condition, Mr. Olsen receives Social
12 Security disability benefits.

13 48. Mr. Olsen is enrolled in Medicare Part B and, each month,
14 Medicare premiums in the amount of \$148.50 are deducted from Mr.
15 Olsen's Social Security disability benefits.

16 49. As a result of Mr. Olsen's payment of the Medicare premiums
17 and enrollment in Medicare Part B, Mr. Olsen is "entitled" to Medicare
18 payment for qualifying claims.
19
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E. Prior Litigation Before This Court

50. The Secretary has previously denied Mr. Olsen's claims for CGM coverage on the grounds that Mr. Olsen's CGM is not "primarily and customarily used to serve a medical purpose."

51. On December 23, 2019, Olsen filed suit after the Secretary issued a final decision denying a claim for coverage.

52. That suit was subsequently transferred to this Court and was styled *Olsen v. Becerra*, E.D. Wa., Case No. 20-cv-374 (SMJ).

53. There, Mr. Olsen sought a reversal of the Secretary's denial, a remand ordering coverage, a declaration that CMS 1682-R issued illegally, and that the Court set aside CMS 1682-R.

54. The parties filed cross-motions for summary judgment.

55. On February 23, 2021, this Court denied the Secretary's motion(s) for summary judgment and granted judgment in Mr. Olsen's favor, finding that a CGM is "primarily and customarily used to serve a medical purpose" and covered "durable medical equipment."

56. The Court's judgment did not address the issue of the illegal issuance of CMS 1682-R.

57. Thereafter, on April 20, 2021, this Court granted Mr. Olsen's requests for attorney's fees.

1 58. In particular, the Court found that the Secretary’s position that
2 a CGM is not “primarily and customarily used to serve a medical purpose”
3 was frivolous and in bad faith.

4 59. In addition, the Court found that the Secretary’s representative
5 (Mr. Bickford) had also engaged in bad faith mischaracterizations in
6 attempting to switch the bases for denial of Mr. Olsen’s claims.

7 60. The Court awarded “bad faith” attorney’s fees pursuant to 28
8 U.S.C. § 2412(b) at market rates in an amount in excess of \$68,000.

9 **V. The Claims at Issue in this Case**

10 61. This case relates to two claims for CGM coverage submitted
11 by Mr. Olsen denied on the same “bad faith” grounds as was the subject of
12 the prior case before this Court (hereinafter, “*Olsen I*”).

13 62. In addition, the Secretary’s conduct (including efforts to evade
14 and/or delay judicial review) in considering Mr. Olsen’s claims after *Olsen*
15 *I* were also in bad faith, separately constitute additional breaches of the law,
16 and demonstrate that the Secretary is not a neutral decision maker in
17 considering CGM claims.

18 **A. April 19 – July 18, 2019 Claim –** 19 **ALJ Appeal No. 3-8946502107/M-20-1269**

20 63. For the period April 19 – July 18, 2019, Mr. Olsen received a
90 day supply of sensors for use with his CGM.

1 64. Mr. Olsen's claim was rejected initially, on redetermination, on
2 reconsideration, and by an ALJ in a decision dated January 31, 2020 all on
3 the "bad faith" grounds.

4 65. Mr. Olsen timely appealed to the MAC.

5 66. On October 22, 2021, the MAC issued a decision denying Mr.
6 Olsen's claim, again, on the "bad faith" grounds.

7 **B. March 10, 2021 Claim – ALJ Appeal No. 3-10205345873**

8 67. On March 10, 2021, Mr. Olsen received a 90-day supply of
9 sensors for use with his CGM.

10 68. The amount of the claim was \$1,824.90.

11 69. Mr. Olsen's claim for coverage was rejected initially on the
12 "bad faith" grounds and no other.

13 70. Mr. Olsen's claim for coverage was rejected on
14 redetermination on the "bad faith" grounds and no other.

15 71. Mr. Olsen sought reconsideration on the grounds that CMS
16 1682-R issued illegally and could not be used to deny his claim.

17 72. On August 24, 2021, Mr. Olsen's claim for coverage was
18 rejected on reconsideration on the "bad faith" grounds and no other.

19

20

1 73. As a result of the continued denial of his claims on the “bad
2 faith” grounds, Mr. Olsen retained an attorney to re-litigate the issues
3 already determined by this Court.

4 74. Pursuant to 42 U.S.C. § 1395ff(b)(2) and 42 C.F.R. § 405.990,
5 Mr. Olsen sought to utilize the “expedited access to judicial review
6 procedure.”

7 75. Thus, Mr. Olsen responded to the denial of his request for
8 reconsideration by contemporaneously filing a request for ALJ review
9 (September 7, 2021) and a request for “expedited access to judicial review”
10 with the Departmental Appeals Board (DAB) (September 8, 2021).

11 76. On October 1, 2021, Mr. Olsen received a “Medicare Summary
12 Notice” (MSN) indicating Medicare’s intention to pay some 13 CGM claims
13 submitted by Mr. Olsen going back more than 3 years, including claim
14 denials that Mr. Olsen failed (though inadvertence) to appeal.

15 77. Included on the October 1, 2021, MSN were the claims at issue
16 in this case.

17 78. Pursuant to 42 C.F.R. § 405.352, if the Secretary determines
18 that he has overpaid a claim, the Secretary can recoup overpayments by
19 deducting monies from government benefits otherwise due the beneficiary,
20 including Social Security disability benefits.

1 **1. October 30, 2021, Decision of ALJ Jason Earnhart**

2 79. On September 7, 2021, through his counsel, Mr. Olsen filed a
3 request for ALJ review limited solely to the issue of whether the “bad faith”
4 denial was proper because CMS 1682-R issued illegally.

5 80. On October 8, 2021, ALJ Jason Earnhart held a hearing, where
6 Mr. Olsen was represented by counsel.

7 81. On October 30, 2021, ALJ Earnhart issued a decision denying
8 Mr. Olsen’s claim.

9 82. ALJ Earnhart held that a CGM is “medically necessary” for
10 Mr. Olsen’s condition.

11 83. Nevertheless, ALJ Earnhart also held that he was “bound by
12 CMS 1682-R to find that” Mr. Olsen’s CGM was non-covered.

13 84. ALJ Earnhart noted that items not falling within CMS 1682-
14 R’s construction of “primarily and customarily used to serve a medical
15 purpose” are ascribed certain codes, including A9276 (sensors), A9277
16 (transmitter), and A9278 (receiver).²

17
18 ² While not the subject to this suit at this time, Plaintiff notes that he
19 submitted a claim for his regular three-month supply of sensors received on
20 October 15, 2021. On November 11, 2021, Mr. Olsen received a notice

1 85. Accordingly, based solely on CMS 1682-R, ALJ Earnhart
2 denied coverage.

3 **2. November 2, 2021 Departmental Appeals Board Decision**

4 86. On September 8, 2021, through his counsel, Mr. Olsen sought
5 “expedited access to judicial review.”

6 87. There, Mr. Olsen noted that the only basis for denial of his
7 claim through reconsideration was the illegally issued CMS 1682-R and that
8 ALJs and the MAC are bound by CMS Rulings and cannot find them
9 invalid.

10 88. On November 2, 2021, the Appellate Division of the
11 Departmental Review Board (DAB) issued a decision denying Mr. Olsen’s
12 request for Expedited Access to Judicial Review, pursuant to 42 U.S.C. §
13 1395ff(b)(2).

14 89. There, the DAB held that because there might be some other,
15 unasserted, grounds on which Mr. Olsen’s claim might be denied, Mr.

16 _____
17 indicating that his sensors had been coded A9276 (i.e., categorized as not
18 “durable medical equipment”) and also indicating that there was no
19 documentation that Mr. Olsen needed his regular three-month supply of
20 sensors.

1 Olsen could not establish that “but for” the illegal CMS 1682-R, Mr.
2 Olsen’s claim would be approved.

3 90. The DAB decision did not reference the prior decision of ALJ
4 Earnhart or identify any basis, other than CMS 1682-R, on which Mr.
5 Olsen’s claim had been rejected.

6 VI. CAUSES OF ACTION

7 COUNT I

8 **Violation of 5 U.S.C. § 706(1)**
(unlawfully withheld or unreasonably delayed)

9 91. Paragraphs 1-90 are incorporated by reference as if fully set
10 forth herein.

11 92. Based on the foregoing, Plaintiffs ask the Court to reverse the
12 Secretary’s Decisions and issue an order finding that a CGM and its related
13 supplies are covered durable medical equipment and direct the Secretary to
14 make appropriate payment for the claims that are the subject of this case.

15 93. Based on the foregoing, Plaintiffs ask the Court to reverse the
16 Secretary’s Decisions as unlawfully withheld or unreasonably delayed and
17 unsupported by the evidence, and issue an order finding that a CGM and its
18 related supplies covered durable medical equipment and direct the Secretary
19 to make appropriate payment for the claims that are the subject of this case.
20

COUNT II

Violation of 5 U.S.C § 706(2)(A)

(arbitrary and capricious, abuse of discretion, not in accordance with law)

94. Paragraphs 1-90 are incorporated by reference as if fully set forth herein.

95. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

96. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that a CGM and its related supplies covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT III

Violation of 5 U.S.C § 706(2)(C)

(in excess of statutory jurisdiction, authority, or limitations or short of statutory right)

97. Paragraphs 1-90 are incorporated by reference as if fully set forth herein.

98. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions and issue an order finding that a CGM and its related

1 supplies are covered durable medical equipment and direct the Secretary to
2 make appropriate payment for the claims that are the subject of this case.

3 99. Based on the foregoing, Plaintiffs ask the Court to reverse the
4 Secretary's Decisions as in excess of the Secretary's authority and
5 limitations and short of Plaintiffs' statutory rights and issue an order finding
6 that a CGM and its related supplies covered durable medical equipment and
7 direct the Secretary to make appropriate payment for the claims that are the
8 subject of this case.

9 **COUNT IV**
10 **Violation of 5 U.S.C § 706(2)(D)**
(without observance of procedure required by law)

11 100. Paragraphs 1-90 are incorporated by reference as if fully set
12 forth herein.

13 101. Based on the foregoing, Plaintiffs ask the Court to reverse the
14 Secretary's Decisions and issue an order finding that a CGM and its related
15 supplies are covered durable medical equipment and direct the Secretary to
16 make appropriate payment for the claims that are the subject of this case.

17 102. Based on the foregoing, Plaintiffs ask the Court to reverse the
18 Secretary's Decisions as done without observance of the procedure required
19 by law (e.g., notice and comment required for modification of LCDs) and
20 issue an order finding that a CGM and its related supplies covered durable

1 medical equipment and direct the Secretary to make appropriate payment
2 for the claims that are the subject of this case.

3 **COUNT V**
4 **Violation of 5 U.S.C § 706(2)(E)**
(not supported by substantial evidence)

5 103. Paragraphs 1-90 are incorporated by reference as if fully set
6 forth herein.

7 104. Based on the foregoing, Plaintiffs ask the Court to reverse the
8 Secretary's Decisions and issue an order finding that a CGM and its related
9 supplies are covered durable medical equipment and direct the Secretary to
10 make appropriate payment for the claims that are the subject of this case.

11 105. Based on the foregoing, Plaintiffs ask the Court to reverse the
12 Secretary's Decisions as not supported by substantial evidence and issue an
13 order finding that a CGM and its related supplies covered durable medical
14 equipment and direct the Secretary to make appropriate payment for the
15 claims that are the subject of this case.

16 **COUNT VI**
17 **Deprivation of Property Interest in Without**
18 **Procedural and Substantive Due Process**
19 **Under the United States Constitution**

20 106. Paragraphs 1-90 are incorporated by reference as if fully set
forth herein.

1 107. Pursuant to the Fifth and Fourteenth Amendments to the
2 Constitution of the United States, Mr. Olsen has a right not to be “deprived
3 of life, liberty, or property without due process of law.”

4 108. As a result of his payment of Medicare premiums, Mr. Olsen
5 has a Constitutionally protected property interest in funds due as a result of
6 qualifying claims submitted to Medicare.

7 109. Mr. Olsen has been deprived his property interest in this
8 regard without due process because the Secretary has not appointed a
9 neutral decision maker to consider Mr. Olsen’s claims.

10 110. The decisions of the ALJs and the MAC are controlled by the
11 Secretary’s “bad faith” policy.

12 111. The decision of the Departmental Appeals Board with regard
13 to “expedited access to judicial review” is in “bad faith” and not reflective
14 of a neutral decision maker.

15 112. Thus, the decisions denying Mr. Olsen’s claims (including his
16 claim to “expedited access”) are not decisions of neutral decision makers,
17 and Mr. Olsen’s due process rights under the Constitution have been
18 violated.

19
20

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court:

A. Enter an order:

(1) setting aside CMS-1682-R (and those portions of LCD L33822 and LCA A52464 that depend on it) and its determination that CGMs that do not completely replace finger prick/test strips are not DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(2) enjoining the Secretary from enforcing CMS 1682-R (and those portions of LCD L33822 and LCA A52464 that depend on it) ad from otherwise denying CGM claims on the grounds that a CGM is not “durable medical equipment”;

(3) finding that CGMs (whether they completely replace finger prick/test strips or not) are DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(4) finding the Secretary’s denials of CGM coverage on the grounds that a CGM is not DME is not supported by substantial evidence, are arbitrary and capricious, an abuse of discretion, and not in accordance with the law;

1 (5) pursuant to 42 U.S.C. § 405(g) (fourth sentence)
2 remanding this matter to the Secretary with instruction to provide coverage
3 for claims at issue in this case; and

4 (6) appointing a special master to monitor the Secretary's
5 compliance with the Court's Order and review (prior to delivery to
6 beneficiaries) any rejection of CGM claims on the grounds that a CGM is
7 not "durable medical equipment), such a special master having the
8 authority to reverse a denial by the Secretary on these grounds, the special
9 master to serve for a period of two years;

10 B. Award attorney's fees and costs to Plaintiffs as permitted by law;

11 and

12 C. Such further and other relief (including nominal damages) this

13 Court deems appropriate.

14 DATED: November 18, 2021

15
16 BRESKIN JOHNSON & TOWNSEND, PLLC

17 By: s/Roger M. Townsend

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1 AND

2 *Pro Hac Vice motion forthcoming:*

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